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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/587,735   | 08/06/2007  | Gary Ruvkun          | 00786/453002                    | 2515                        |
| 21559  | 7590        | 09/03/2009           |                                 |                             |
| CLARK & ELBING LLP<br>101 FEDERAL STREET<br>BOSTON, MA 02110 |             |                      | EXAMINER<br>CHONG, KIMBERLY     |                             |
|  |             |                      | ART UNIT<br>1635                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>09/03/2009 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/587,735 | <b>Applicant(s)</b><br>RUVKUN ET AL. |  |
|                              | <b>Examiner</b><br>KIMBERLY CHONG    | <b>Art Unit</b><br>1635              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 6-7, 9-10, drawn to a method for identifying a mutation in a nucleic acid molecule encoding a polypeptide that inhibits RNAi comprising providing a mutagenized nematode, contacting said nematode with an inhibitory oligonucleotide and detecting a decrease in expression.

Group II, claim(s) 6, 8-10, drawn to a method for identifying a mutation in a nucleic acid molecule encoding a polypeptide that inhibits RNAi comprising providing a mutagenized cell wherein the cell is a mammalian cell, contacting said cell with an inhibitory oligonucleotide and detecting a decrease in expression.

Group III, claim(s) 11-15, drawn to a method for identifying a candidate compound that enhances RNAi comprising providing a cell expressing an eri-1 nucleic acid molecule.

Group IV, claim(s) 16-25, drawn to a method for identifying a candidate compound that enhances RNAi comprising providing a cell expressing an ERI-1

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polypeptide. This group is subject to a species election of a cell and detection of biological activity.

Group V, claim(s) 26, 34-35, drawn to a method for identifying a candidate compound that enhances RNAi comprising providing an ERI-1 polypeptide.

Group VI, claim(s) 27-30, drawn to a method for identifying a candidate compound that enhances RNAi comprising providing an ERI-1 polypeptide and a nucleic acid substrate.

Group VII, claim(s) 31, drawn to a method for identifying a candidate compound that enhances RNAi comprising providing a cell expressing an ERI-1 polypeptide and contacting said cell with a dsRNA in the presence of said candidate compound.

Group VIII, claim(s) 32, drawn to an isolated ERI-1 polypeptide comprising an amino acid sequence having at least 90% identity to the nucleotide sequence encoding SEQ ID No. 2.

Group IX, claim(s) 33, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 90% identity to the nucleotide sequence encoding SEQ ID No. 2.

Group X, claim(s) 36, drawn to an antibody that specifically binds to an ERI-1 polypeptide.

Group XI, claim(s) 37-40, drawn to an organism comprising a mutation in an eri-1 nucleic acid sequence. This group is subject to a species election of an organism.

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Group XII, claim(s) 41-62, 72, 73, and 76, drawn to an isolated nucleobase oligomer comprising a duplex comprising 8-30 consecutive nucleobases of an eri-1 nucleic acid.

Group XIII, claim(s) 63-66, drawn to a transgenic organism expression a nucleic acid sequence encoding an eri-1 nucleobase oligomer. This group is subject to a species election of an organism.

Group XIV, claim(s) 63-66, drawn to a method for enhancing RNAi in an organism comprising contacting said organism with a nucleobase oligomer targeted to eri-1 gene. This group is subject to a species election of an organism.

Group XV, claim(s) 74, drawn to an antisense nucleic acid molecule targeted to an eri-1 nucleic acid.

Group XVI, claim(s) 75, drawn to a method for identifying an siRNA having enhanced RNAi activity.

Group XVII, claim(s) 77, drawn to an isolated eri-1 inhibitory nucleic acid comprising at least a portion of a naturally occurring eri-1 nucleic acid molecule of an organism wherein the nucleic acid encodes a polypeptide selected from the group as listed. This group is subject to a species election of a polypeptide.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Groups I-XVII lack unity of invention because the groups do not share the same or corresponding technical feature. Groups I-VI, XIV and XVI are drawn to methods of identifying a mutation in a nucleic acid molecule and methods of enhancing RNAi wherein each comprise special technical features of different cells lines and different compounds used in the methods. The special technical feature of groups VIII-XIII, XV and XVII are an isolated polypeptide having SEQ ID No. 2, and isolated nucleic acid sequence capable of expression SEQ ID No. 2, an antibody, an organism, a dsRNA that targets eri-1, a transgenic organism an antisense targeted to eri-1 and an isolated eri-1 nucleic acid encoding a protein as claimed, respectively, which are not shared. Thus, the inventions do not relate to a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 17-20 are drawn to distinct cells and one must be selected. Claims 22-24 are drawn to distinct detection methods of biological activity and one must be selected. Claims 38-40, 64-66 and 68-70 are drawn to different organisms and one must be selected. Claim 77 is drawn to eri-1 polypeptides and one must be selected.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

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must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: **[2]**.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service



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center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
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